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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOSEPH R. BYRUM

Appeal 2008-2456
Application 09/552,087
Technology Center 1600

Decided: September 26, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 3, 5-7, 9, 10, and 12-20, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a transformed plant cell (claims 3, 5, and 6); a transformed plant (claims 7, 9, and 10); and a substantially purified nucleic acid molecule (claims 12-20). Claim 12 is illustrative:

> 12. A substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 70% identity with a nucleic acid sequence of SEQ ID NO: 1 or the complement thereof.

The Examiner relies on the following prior art to support the rejections of record.

Omilli et al., *Sequences Involved in Initiation of Simian Virus 40 Late Transcription in the Absence of T Antigen*, 6 MOL. CELL. BIOL. 1875-1885 (1986).

Pietrzkowski et al., *Characterization of an Enhancer-like Structure in the Promoter Region of the Proliferating Cell Nuclear Antigen (PCNA) Gene*, 193 EXP. CELL. RES. 283-290 (1991).

Chan et al., *Promoter analysis of the nuclear gene encoding the chloroplast glyceraldehyde-3-phosphate dehydrogenase B subunit of Arabidopsis thaliana*, 46 PLANT MOL. BIOL. 131-141 (2001).

NCBI Sequence Viewer, Accession No. AF147259, http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=4732164, accessed April 22, 2008.

The rejections as presented by the Examiner are as follows[1]:

Claims 3, 5-7, 9, 10, and 12-20 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.

Claims 3, 5-7, 9, 10, and 12-20 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We affirm.

PROCEDURAL HISTORY

This is the second appeal of the subject matter of this Application. In the previous Appeal (Appeal No. 2004-1772) we reversed a written description rejection and remanded the application to the Examiner to reconsider the rejections under 35 U.S.C. § 101 and under the enablement provision of 35 U.S.C. § 112, first paragraph as lacking a patentable utility (*see* 2004-1772 Decision 2).

DISCUSSION

Utility:

Claims 3, 5-7, 9, 10, and 12-20 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of

[1] We recognize that the Examiner set out two separate rejections under the enablement provision of 35 U.S.C. § 112, first paragraph (*see* Ans. 11-12). The first, presented at page 11 of the Answer is a corollary to the Examiner's finding of lack of utility (*see* Ans. 3). Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the first rejection under the enablement provision of 35 U.S.C. § 112, first paragraph, which is based on the Examiner's finding of lack of utility.

35 U.S.C. § 112, first paragraph based on the finding of lack of utility. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Therefore, we limit our discussion to representative claim 12.

Claim 12 is drawn to a substantially purified nucleic acid molecule. Claim 12 requires that the nucleic acid molecule have between 70-100% identity with the nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

According to the Examiner, while Appellant's Specification "discloses a number of general utilities for the nucleic acids disclosed herein . . . [n]one of these asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequences being claimed" (Ans. 4).

Appellant disagrees, asserting instead that "[t]he utility of SEQ ID NO: 1 is *specific* because it is specific to SEQ ID NO: 1 and not generally to any nucleic acid sequence" (App. Br. 7). In this regard, Appellant asserts that a specific utility of SEQ ID NO: 1 was confirmed "by conducting a BLASTN analysis", which "show that SEQ ID NO: 1 has 95 percent identity to a sequence obtained from *Glycine max* (soybean)" (App. Br. 6).

Appellant asserts that SEQ ID NO: 1 "shares 95 percent identity to a sequence obtained from *Glycine max* and this sequence was generated from soybean root hair tissue treated with *Bradyrhizobium japonicum* for 24 hours" (App. Br. 7). According to Appellant

> [t]his utility is *substantial* and *credible* because SEQ ID NO: 1 can be used to isolate genes, map genes, and determine gene function associated with nitrogen fixation because it is well

> known to one of ordinary skill in the art that *B. japonicum* is a gram negative, nitrogen-fixing bacterium belonging to the Rhizobiaceae family.

(*id.*) In this regard, Appellant asserts that "*B. japonicum* and *Glycine max* have a symbiotic relationship and *B. japonicum* helps *Glycine max* fix nitrogen, *i.e.,* convert nitrogen gas into a form readily utilized by the plant. The result of this symbiosis is a dramatic increase in plant production without the need for adding external fertilizer" (App. Br. 7-8).

However, as the Examiner points out Appellant's assertion that

> SEQ ID NO: 1 can be used to isolate genes, map genes, and determine gene function associated with nitrogen fixation because it is well known that *B. japonicum* is a gram negative, nitrogen-fixing bacterium belonging to the Rhizobiaceae family . . . is not [a utility that is] set forth in the specification, therefore, it is not an asserted utility provided at the time of filing of the application.

(Ans. 22.) We agree. "Enablement, or utility, is determined as of the application filing date." *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995).

In addition, the Examiner finds that the 95% sequence identity that Appellant relies upon is not over the full length of SEQ ID NO: 1, but instead is over a stretch of 105 nucleotides, which is less than 1/3 the 394 nucleotide length of SEQ ID NO: 1 (Ans. 21). According to the Examiner, "[e]ven knowing that these two molecules share a portion of identity does not tell one of skill in the art that SEQ ID NO: 1 itself is involved in nitrogen fixation" (*id.* at 23). We find no error in the Examiner's conclusion that this limited region of sequence identity is insufficient to support a conclusion that SEQ ID NO: 1 is functionally related to a polynucleotide from *Glycine max* (*id.* at 22).

For the foregoing reasons we are not persuaded by Appellant's assertion that because a small portion of SEQ ID NO: 1 shares 95 percent identity to a sequence obtained from *Glycine max* the utility of their claimed invention is satisfied because SEQ ID NO: 1 can be used to isolate genes, map genes, and determine gene function associated with nitrogen fixation. (*See, e.g.,* App. Br. 7).

To be complete, we recognize Appellant's assertion that "[t]he specification as filed clearly disclosed that isolation and mapping of genes and determining gene function associated with the nucleic acid molecules of the invention is are [sic] stated utilities of the invention. . . . Nitrogen fixation is merely an example of such a utility" (App. Br. 9). We note, however, that Appellant did not identify and we do not find a portion of Appellant's Specification that would direct a person of ordinary skill in this art to use SEQ ID NO: 1 for any purpose related to nitrogen fixation. Accordingly, we are not persuaded by Appellant's assertion.

All of Appellant's arguments are based on the asserted relationship between SEQ ID NO: 1 and a sequence from *Glycine max*. For the foregoing reasons, we are not persuaded by these arguments. Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief ... will be refused consideration by the Board, unless good cause is shown.").

Accordingly, we affirm the rejection of claim 12 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility. Because they are not separately argued, claims 3, 5-7, 9, 10, and 13-20 fall together with claim 12.

Enablement:

Claims 3, 5-7, 9, 10, and 12-20 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Therefore, we limit our discussion to representative claim 12.

According to the Examiner the subject matter of claim 12 "was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention" (Ans. 12). In this regard, the Examiner finds that Appellant's "specification teaches that the disclosed SEQ ID NO: 1 may comprise regulatory elements (p. 16), may comprise genes encoding polypeptides or fragments thereof (p. 24) or may comprise introns and/or intron/exon junctions (p. 29)" (*id.* at 26). From this the Examiner finds that "[g]iven that the specification asserts that instant SEQ ID NO: 1 may include any or all of these, but fails to even positively identify a single one of these suggested elements within SEQ ID NO: 1, it cannot be definitely determined if SEQ ID NO: 1 actually contains a promoter or not, based on the teachings of the specification" (*id.*).

In response, Appellant asserts that SEQ ID NO: 1 is 394 nucleotides long and therefore a molecule that has 70% identity to SEQ ID NO: 1 is changed by at most 118 nucleotides (App. Br. 12). In addition, Appellant asserts that a person of ordinary skill in the art would be able to predict how each of the possible 118 nucleotide changes would affect SEQ ID NO: 1 because "conservative nucleic acid substitutions generally retain

functionality while non-conservative substitutions generally do not" (*id.*) We are not persuaded.

As the Examiner explains, "[w]ithout knowing the function of SEQ ID NO: 1, one cannot predict how that function might change with any substitution, conservative or not" (Ans. 27). We agree. In the absence of a specific and substantial utility for the invention of claim 12, it is unclear what, if any, modifications could be made to the claimed sequence. For example, we find that it would be reasonably clear to a person of ordinary skill in this art that more extensive modification can be made to SEQ ID NO: 1 if it were an intron as opposed to a regulatory element or protein encoding sequence.

Therefore, we agree with Appellant that "the issue is not whether 118 substitutions are large or not, but rather whether one of ordinary skill in the art can reasonably predict, without undue experimentation, what the effects of those substitutions would be" (App. Br. 13). The problem with Appellant's argument, however, is that without a clear understanding of the use of SEQ ID NO: 1, one of ordinary skill in this art *cannot* reasonably predict, without undue experimentation, what the effects of any substitution would be.

For the foregoing reasons, we affirm the rejection of claim 12 under the enablement provision of 35 U.S.C. § 112, first paragraph. Because they are not separately argued, claims 3, 5-7, 9, 10, and 13-20 fall together with claim 12.

CONCLUSION

In summary, we affirm the rejections of record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

cdc

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